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EXAMINER

FINK, BRIEANN R

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/583,506	Applicant(s) MATSUMOTO ET AL.	
	Examiner Briann R. Fink	Art Unit 1796	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 January 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4,6-9,11 and 12 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4,6-9,11 and 12 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. This office action follows a reply filed on January 28, 2009. Claims 1 and 7 have been amended. Claims 1-4, 6-9, and 11-12 are currently pending and under examination.
2. The texts of those sections of Title 35 U.S. Code are not included in this section and can be found in a prior Office action. The rejections below are the same as those presented in the prior office action.
3. Claims 7-9 and 12 are rejected under 35 U.S.C. 102(b) as being anticipated by *Yanagawa et al.* (US 5,041,511).

Yanagawa et al. discloses an ocular lens material, used for contact lenses (col. 1, ll. 1-4) consisting of a (meth)acrylic monomer, styrene monomer, other monomers, and a cross linking agent (col. 1, ll. 43-47). More specifically, a fluorine-containing (meth)acrylic monomer such as 2,2,2-trifluoroethyl (meth)acrylate (col. 3, ll. 42-52), a silicon-containing monomer such as tris(trimethylsiloxy)silylstyrene (col. 6, ll. 4-18), and crosslinking agents such as ethylene glycol di(meth)acrylate (col. 8, ll. 1-3) or 4-vinylbenzyl (meth)acrylate (col. 1, l. 61-col. 2, l. 2). The silicon-containing styrene is preferably within a range of from 30 to 90 parts by weight, and the fluorine-containing (meth)acrylate is preferably within a range of 10 to 70 parts by weight (col. 9, ll. 36-40). The amount of crosslinking agent is within a range of 0.5 to 15 parts by weight (col. 8, ll. 24-27). *Yanagawa et al.* also discloses that an ultraviolet absorber or colorant

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can be added to the lens material (col. 9, ll. 4-8). The resulting polymers have oxygen permeability coefficients of at least $200 \cdot 10^{-11}$ (mL•cm²)/(cm³•sec•mmHg) (Examples 4-6).

4. Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over *Yanagawa et al.* (US 5,041,511), as applied to claims 7 and 8 above.

As noted, *Yanagawa et al.* anticipates claims 7 and 8, but fails to teach the amount of unpolymerized monomer content and the water absorption ratio of the copolymer.

The amount of unpolymerized monomer content is implied in the structure of the polymer, which is inherent in the structure of the copolymer taught by *Yanagawa et al.*

Yanagawa et al. teaches that the incorporation of monomers with hydrophilic groups, such as (meth)acrylic acid, improve the hydrophilicity of a contact lens or to obtain a water absorptive soft ocular lens material (col. 8, ll. 59-61). The omission of an element is obvious if the function of the element is not desired. See MPEP 2144.04 IIA.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have omitted the hydrophilic monomer, (meth)acrylic acid, in order to remove its function taught by *Yanagawa et al.*

5. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over *Yanagawa et al.* (US 5,041,511), as applied to claims 7 and 8 above, and further in view of *Mukoyama* (JP 08-304746).

As noted, *Yanagawa et al.* anticipates claims 7 and 8. *Yanagawa et al.* also teaches that the polymerization is conducted by gradually heating or raised stepwise within a temperature range of from room temperature to 130°C or through radiation of electromagnetic rays (col. 9, ll. 54-60); however *Yanagawa et al.* fails to teach the time period over which the polymerization is conducted.

Mukoyama teaches a contact lens material that is polymerized using a silicone-containing styrene monomer, a fluorine-containing (meth)acrylate, and a monomer for dimensional stability, such as the applicant's crosslinking agent ethylene glycol dimethacrylate ([0025], [0020], [0033]). *Mukoyama* further teaches the method of polymerizing the components through Working Example 1 where the mixture was irradiated at a temperature between 40 and 50°C for one hour to obtain a transparent copolymer.

It would have been obvious to one skilled in the art at the time of the invention to have polymerized the polymer composition of *Yanagawa et al.* as suggested by *Mukoyama* because it results in the same polymer composition at in a short amount of time.

6. Claim 1-4 and 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over *Yanagawa et al.* (US 5,041,511).

Yanagawa et al. discloses an ocular lens material, used for contact lenses (col. 1, ll. 1-4) consisting of a (meth)acrylic monomer, styrene monomer, other monomers, and a crosslinking agent (col. 1, ll. 43-47). More specifically, *Yanagawa et al.* teaches a copolymer of comprising a fluorine-containing alkyl

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(meth)acrylic monomer (col. 3, ll. 42-52), a silicon-containing styrene monomer (col. 6, ll. 4-18), and crosslinking agents (col. 8, ll. 1-28, and col. 1, l. 61-col. 2, l. 2). The silicon-containing styrene is preferably within a range of from 30 to 90 parts by weight, and the fluorine-containing (meth)acrylate is preferably within a range of 10 to 70 parts by weight (col. 9, ll. 36-40). The amount of crosslinking agent is within a range of 0.5 to 15 parts by weight (col. 8, ll. 24-27). *Yanagawa et al.* further discloses that an ultraviolet absorber or colorant can be added to the lens material (col. 9, ll. 4-8). The resulting polymers result in oxygen permeability coefficients of at least $200 \cdot 10^{-11}$ (mL \cdot cm²)/(cm³ \cdot sec \cdot mmHg) (Examples 4-6).

Yanagawa et al. fails to teach the amount of unpolymerized monomer content and the water absorption ratio of the copolymer.

The amount of unpolymerized monomer content is implied in the structure of the polymer, which is inherent in the structure of the copolymer taught by *Yanagawa et al.*

Yanagawa et al. teaches that the incorporation of monomers with hydrophilic groups, such as (meth)acrylic acid, improve the hydrophilicity of a contact lens or to obtain a water absorptive soft ocular lens material (col. 8, ll. 59-61). The omission of an element is obvious if the function of the element is not desired. See MPEP 2144.04 IIA.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have omitted the hydrophilic monomer, (meth)acrylic acid, in order to remove its function taught by *Yanagawa et al.*

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7. Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over *Yanagawa et al.* (US 5,041,511), as applied above to claims 1-4 and 6, further in view of *Mukoyama* (JP 08-304746).

Yanagawa et al. renders claims 1-3 as obvious as noted above, but fails to teach the time period needed to complete polymerization.

Mukoyama teaches a contact lens material that is polymerized using a silicone-containing styrene monomer, a fluorine-containing (meth)acrylate, and a monomer for dimensional stability, such as the applicant's crosslinking agent ethylene glycol dimethacrylate ([0025], [0020], [0033]). *Mukoyama* further teaches the method of polymerizing the components through Working Example 1 where the mixture was irradiated at a temperature between 40 and 50°C for one hour to obtain a transparent copolymer.

It would have been obvious to one skilled in the art at the time of the invention to have polymerized the polymer composition of *Yanagawa et al.* as suggested by *Mukoyama* because it results in the same polymer composition at in a short amount of time; hence, *Yanagawa et al.* in view of *Mukoyama* suggests such a product.

The rejections , as set forth in the previous office action, are deemed proper and are therefore maintained.

Response to Arguments

8. Applicant's arguments, see p. 8-10, filed January 28, 2009 have been fully considered but they are not persuasive.

a. The applicants' amendments to claims 1 and 7 define the product by how the product was made. Thus, claims 1 and 7 are product-by-process claims. For purposes of examination, product-by-process claims are not limited to the manipulation of the recited steps, only the structure implied by the steps. See MPEP 2113.

In the present case, the recited steps imply a structure having a silicon-containing contact lens material with a residual amount of unpolymerized monomer of no more than 3.5% by weight and an oxygen permeability of at least $130 \times 10^{-11} \text{ (cm}^2\text{/sec) \cdot (mLO}_2\text{)/(mL \cdot mmHg)}$ and a water absorption ratio of the copolymer is at most 0.3% by weight. The reference, *Yanagawa et al.*, suggests such a product.

b. The applicants argue that the references applied do not teach or suggest the two-step polymerization process which was added upon amendment. This two-step polymerization process is commonly employed by those skilled in the art in order to minimize the amount of residual monomer while maintaining a high yield of product in a short amount of time. This process is taught generally by *Yanagawa et al.* and *Ito et al.* (WO 00/70388, using citations from the English

language equivalent ,US 2004/0054106, for convenience) and is given meaning by *Baba et al.* (US 2002/0198280), as explained below.

Yanagawa et al. generally teaches that the copolymer can be polymerized by gradually heating within a temperature range of from room temperature to 130°C, or the temperature may be raised stepwisely (col. 9, ll. 54-60).

Ito et al. teaches typical methods of polymerization for ocular lens material (p. 6, [0093]). One method of polymerization is that of thermal polymerization, and consists of heating the monomer mixture and initiator at about 30 to 60°C for several to several 10 hours to polymerize the mixture, where then the temperature is gradually increased to about 120 to 140°C over several hours to complete the polymerization (p. 6, [0094]). *Ito et al.* teaches that this is a typical method for polymerization for ocular lenses.

Baba et al. teaches a copolymer used for ocular lenses. The monomer mixture and initiator are polymerized with gradual heating by means of a molding method (p. 11, [0132]). The heating temperature is at least between 50 and 60°C in order to decrease the polymerization time as well as the amount of residual monomers (p. 11, [0134]). The temperature is at most between 140 and 150°C to prevent evaporation of the monomeric components (Id.).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have polymerized the ocular lens material of *Yanagawa et al.* with the polymerization method of *Ito et al.* because, as

suggested by *Baba et al.*, it decreases the time needed for polymerization, the amount of residual monomers and further prevents the evaporation of the monomeric components.

Response to Amendment

9. The declaration under 37 CFR 1.132 filed January 28, 2009 is insufficient to overcome the rejection of claims 1 and 7 based upon the rejection under 35 U.S.C. 102(b) as being anticipated by *Yanagawa et al.* and the rejection under 35 U.S.C. 103(a) as being unpatentable over *Yanagawa et al.* in view of *Mukoyama* as set forth in the last Office action because the facts presented are not germane to the rejection at issue.

The applicants argue that the claimed composition can be obtained by a particular polymerization process which is advantageous over the processes of the prior art. The applicant attempted to show this by presenting a variety of examples, all prepared with the same polymerization conditions and with different monomeric compositions, except that of Comparative examples 2 and 3. Comparative example 2 was prepared with polymerization conditions A, which are those of the instant invention, while Comparative example 3 was prepared with polymerization conditions B, which are similar to those of Example 2 of *Yanagawa et al.* (See col. 11, ll. 31-36). Both examples had the same monomeric compositions, allowing for the effect of the polymerization conditions to be compared. The copolymer of Comparative example 2 resulted with the

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following properties, those relating to the claimed invention: a total residual amount of unpolymerized monomer of 8.9% by weight, an oxygen permeability coefficient (Dk) of 172×10^{-11} (cm²/sec)•(mLO₂)/(mL•mmHg), and a water absorption ratio of 3.8%. The copolymer of Comparative example 3 resulted with the following properties, those relating to the claimed invention: a total residual amount of unpolymerized monomer of 2.45% by weight, an oxygen permeability coefficient (Dk) of 170×10^{-11} (cm²/sec)•(mLO₂)/(mL•mmHg), and a water absorption ratio of 2.3%. A comparison of the two examples shows that the polymerization method of the instant invention (with polymerization conditions A) produces copolymers with properties similar to that of the prior art (with polymerization conditions B), and even somewhat less desirable properties than the prior art.

Therefore, the applicant has proven the examiners stance that the prior art teachings, namely those of *Yanagawa et al.*, provide the same copolymer product with the same properties as that of the instant invention. Further, this is all that is required by the examiner to provide a basis of inherency or obviousness for the copolymers of instant claims 1 and 7 due to the claimed product-by-process limitations set forth.

Note that the properties of Comparative examples 2 and 3 do not fall within the claimed ranges of the instant invention; however, the applicants provided no comparative examples where the compositions remain unchanged

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and only that of the polymerization conditions change of temperature and time are varied within the claimed invention.

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Briann R. Fink whose telephone number is (571)270-7344. The examiner can normally be reached on Monday through Friday, 7:00 AM to 4:30 PM (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Randy P. Gulakowski can be reached on (571)272-1302. The fax phone

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number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/B. R. F./
Examiner, Art Unit 1796

/Randy Gulakowski/
Supervisory Patent Examiner, Art Unit 1796